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Applicant	:	Jonathan J. Langberg, et al.	Confirmation No. 2408
Application No.	:	10/806,906	
Filed	:	March 23, 2004	
Title	:	PERCUTANEOUS MITRAL ANNULOPLASTY WITH HEMODYNAMIC MONITORING	
Grp./Div.	:	3774	
Examiner	:	Ann M. Schillinger	
Customer No.	:	30452	
Docket No.	:	PVI-5813CIPCON2/53763/E303	

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
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January 26, 2010

Commissioner:

This is an appeal to the Board of Patent Appeals and Interferences from the final Office Action dated April 27, 2009, in which claims 1-37 stand rejected.

I. REAL PARTY IN INTEREST

Edwards Lifesciences LLC is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences presently pending.

III. STATUS OF CLAIMS

Claims 1-37 are pending in the application.

No claims have been allowed.

The rejection of claims 1-37 is appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed after the final Office Action dated April 27, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1 and 19 are independent. In summarizing the claimed subject matter, Applicants have referred to figures and paragraph numbers of U.S. 2004/0176840, which is the U.S. Patent Application Publication of the present application.

Summary of Claim 1 Subject Matter

Claim 1 is directed to a method of treating a patient. Claim 1 specifies transluminally advancing a prosthesis (*FIG. 1, prosthesis 40*) in a first configuration into the coronary sinus (*FIG. 1, coronary sinus 22*). *See for example, paragraph [0072], last sentence and paragraph [0077], first two sentences.* Claim 1 also specifies manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus. *See for example, paragraph [0056].* Claim 1 then specifies monitoring hemodynamic function while the prosthesis is in the second configuration. *See for example paragraphs [0082] and [0083].* Claim 1 further specifies assessing mitral valve regurgitation in

response to the monitoring step. *See for example, paragraphs [0082] and [0083], and in particular paragraph [0083] regarding "physician's judgment."* Claim 1 additionally specifies adjusting the prosthesis to a third configuration different from the second configuration in response to the assessing step. *See for example, paragraphs [0082] and [0083], and in particular paragraph [0083] regarding "reconfiguration."*

Summary of Claim 19 Subject Matter

Claim 19 is directed to a method of remodeling a mitral valve annulus to reduce mitral valve regurgitation. Claim 19 specifies advancing an adjustable prosthesis (*FIG. 1, prosthesis 40*) in a first configuration to a position adjacent the mitral valve annulus. *See for example, paragraph [0077] and position of prosthesis 40 shown in FIG. 1.* Claim 19 specifies manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation. *See for example, paragraph [0056].* Claim 19 then specifies monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration. *See for example paragraphs [0082] and [0083].* Claim 19 further specifies assessing the degree of regurgitation in response to the monitoring step. *See for example, paragraphs [0082] and [0083], and in particular paragraph [0083] regarding "physician's judgment."* Claim 19 additionally specifies fixing the prosthesis in the second configuration in response to the assessing step. *See for example, paragraphs [0082] and [0083], and in particular paragraph [0083] on page 8 regarding locking the device.*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5, 12, 19, 21-23, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Diederich, et al., (U.S. Patent No. 6,117,101).

Claims 6-11 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Wright (U.S. Patent No. 5,522,884).

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Grimes (U.S. Patent No. 6,312,447).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Purdy et al. (U.S. Patent No. 5,562,729).

Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Fowler, Jr. et al. (U.S. Patent No. 5,086,776).

Claims 15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Killman (U.S. Patent No. 5,846,198).

Claims 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Mehta (U.S. Patent No. 5,476,453).

Claims 17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of McIntyre (U.S. Patent No. 5,291,895).

Claims 18, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich, et al., in view of Kadhiresan (U.S. Patent No. 5,935,081).

VII. ARGUMENT

Applicants have provided a brief description of Diederich, et al., below and as further discussed below submit that claims 1-37 are patentable over Diederich, et al., when considered alone or in combination with the other references applied in the Office Action.

1. Brief Description of Diederich, et al.

Diederich, et al., is directed to "a circumferential ablation device assembly which is adapted to treat patients with atrial arrhythmia by forming a circumferential conduction block in a pulmonary vein which blocks electrical conduction along the longitudinal axis of the pulmonary vein wall and into the left atrium." *See Diederich, et al., col. 11, line 67 to col. 12, line 5.* Referring to Fig. 4 of Diederich, et al., which is reproduced below and modified by Applicants, an ablation element 160 is provided around an expandable member 170. The ablation element is formed with "an 'energy emitting' type which is adapted to emit energy sufficient to ablate tissue when coupled to and energized by an energy source." *See Diederich, et al., col. 13, lines 17-19.* Examples of such "energy emitting" elements include direct current or alternating current electrodes, microwave emitting antenna, a heating element, or an ultrasonic

emitting element capable of emitting sound waves sufficient to ablate tissue. *See Diederich, et al., col. 13, lines 19-34.*

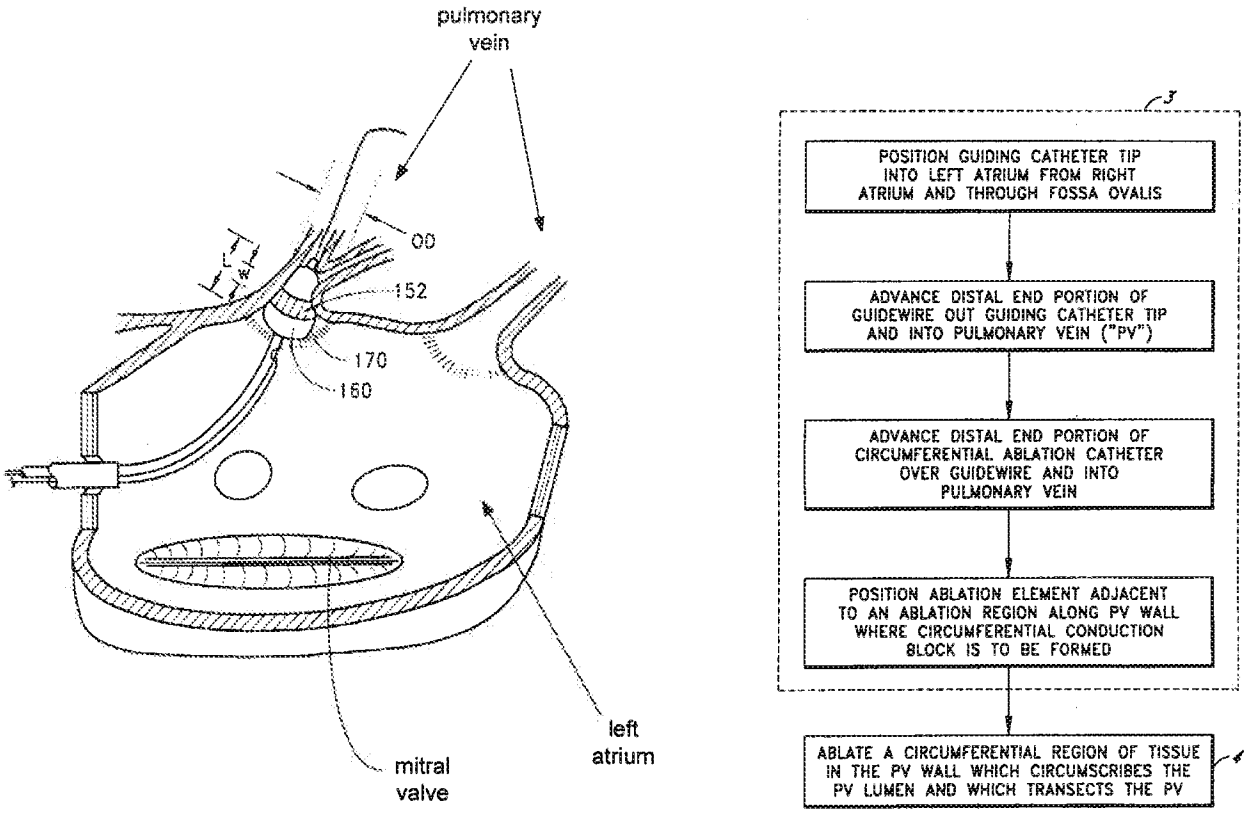

FIG. 4 (left) and FIG. 2 (right) of Diederich, et al., (modified by Applicants)

FIG. 2 of Diederich, et al., which is reproduced above, shows the sequential steps of the method for using the circumferential ablation device in forming a circumferential conduction block in a pulmonary vein. *See Diederich, et al., at col. 14, lines 12-23.* In the positioning step 3, the expandable member 170 is attached to a catheter 101 and a guide wire 102, by which the expandable member is guided through the left atrium to the pulmonary vein. When the expandable member is positioned at the ostium of the pulmonary vein, it is expanded so that the ablation band 152 of the ablation element 160 circumferentially contacts the inner surface of the pulmonary vein. In the ablation step 4, electrical signals are sent to the ablation band 152 in

order to form a conduction block at the pulmonary vein ostium. The conduction block can treat atrial arrhythmia by blocking the path of electrical pulses traveling through the pulmonary vein. *See Diederich, et al., col. 15, line 42 to col. 16 line 56, and col. 19, line 54 to col. 20 line 8.*

2. The Examiner's rejection of claims 1-18 should be reversed.

A. Diederich, et al., does not anticipate claims 1-5 and 12.

Claim 1 is reproduced below with the limitations discussed herein shown underlined:

> A method of treating a patient, comprising the steps of:
> transluminally advancing a prosthesis in a first configuration into the coronary sinus;
> manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus;
> monitoring hemodynamic function while the prosthesis is in the second configuration;
> assessing mitral valve regurgitation in response to the monitoring step; and
> adjusting the prosthesis to a third configuration different from the second configuration in response to the assessing step.

As discussed in detail below, Applicants submit that Diederich, et al., does not describe the above underlined limitations of claim 1.

i. Diederich, et al., does not describe "transluminally advancing a prosthesis in a first configuration into the coronary sinus" as recited in claim 1.

At the outset, Applicants submit that Diederich, et al., does not disclose a prosthesis as recited in claim 1. A "prosthesis" is defined as "a device, either external or implanted, that substitutes for or supplements a missing or defective part of the body.[1]" Diederich, et al., does not describe that the ablation device including the expandable member 170 and the ablation element 160 remains in the body in order to substitute for or supplement a missing or defective body part. Diederich, et al., discloses that the ablation element 160 is removed after forming a circumferential lesion in the pulmonary vein. *See Diederich, et al., at col. 18, lines 6-12.*

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[1] *See prosthesis. Dictionary.com. Dictionary.com Unabridged. Random House, Inc. http://dictionary.reference.com/browse/prosthesis (accessed: October 27, 2009)*

Therefore, Applicants submit that Diederich, et al., does not describe a prosthesis as recited in claim 1.

In rejecting claim 1, the Examiner does not assert that Diederich, et al., discloses "transluminally advancing a prosthesis in a first configuration into the coronary sinus" as recited in claim 1. The only assertion made by the Examiner is that Diederich, et al., discloses "advancing an adjustable prosthesis (100) with a catheter (130) in a first configuration to a position adjacent the mitral valve annulus (Fig. 3; col. 15, lines 42-58)." *See final Office Action, page 2.* However, the limitation that specifies advancing the prosthesis to a position adjacent the mitral valve annulus is recited in claim 19, and is not a part of claim 1. Therefore, the Examiner has rejected claim 1 without asserting that Diederich, et al., discloses "transluminally advancing a prosthesis in a first configuration into the coronary sinus."

Furthermore, Diederich, et al., does not describe "transluminally advancing a prosthesis in a first configuration into the coronary sinus." Diederich, et al., discloses in detail the method of accessing the pulmonary vein. *See Diederich, et al., at col. 14, line 23 to col. 15, line 26.* However, Diederich, et al., does not describe that the method of accessing the pulmonary vein includes advancing a catheter, a guide wire, and/or the ablation device *into the coronary sinus.* Diederich, et al., describes two methods of reaching the pulmonary vein. One method is by inserting the catheter in the right atrium and then inserting the catheter into the left atrium through the fossa ovalis. *See Diederich, et al., col. 14, lines 23-49.* In an alternative method, the catheter is "advanced through the aorta, around the aortic arch, into the ventricle, and then into the left atrium through the mitral valve." *See Diederich, et al., col. 14, lines 50-61.* After accessing the pulmonary vein, Diederich, et al., discloses the following regarding the positioning step of the ablation device:

> Subsequent to gaining pulmonary vein access, positioning step (3) of FIG. 2 next includes tracking the distal end portion of a circumferential ablation device assembly over the guidewire and into the pulmonary vein, followed by positioning a circumferential ablation element at an ablation region of the pulmonary vein where the circumferential conduction block is to be desirably formed.

See Diederich, et al., at col. 15, lines 27-41.

Upon reaching the pulmonary vein, Diederich's ablation element is positioned at an ablation region of the pulmonary vein where the conduction block is to be desirably formed. Therefore, the ablation device of Diederich, et al., including the expandable member 170 and the ablation element 160 is not advanced into the coronary sinus during the process of accessing the pulmonary vein or after the ablation device is positioned at a desired location in the pulmonary vein.

Based on the foregoing, Applicants submit that Diederich, et al., does not describe "transluminally advancing a prosthesis in a first configuration into the coronary sinus."

ii. Diederich, et al., does not describe "manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus" as recited in claim 1.

In rejecting claim 1, the Examiner asserts that Diederich, et al., discloses "manipulating the prosthesis from the first configuration toward a second configuration that exerts a compressive force against the mitral valve annulus with a forming element (175) (Fig. 4; col. 16, lines 3 1-56)." *See final Office Action, page 2.* Referring to FIG. 4 of Diederich, et al., which is reproduced below and modified by Applicants, the expandable member 170 of the ablation device is expanded by the expansion actuator 175 (shown in FIG. 4 of Diederich, et al.) after being positioned at a desired location in the pulmonary vein. *See Diederich, et al., at col. 16, lines 31-36.* The outer diameter of the expandable member 170 when expanded is "sufficient to engage a body space wall or adjacent ablation region surrounding the expandable member, at least on two opposing internal sides of the body space wall or adjacent ablation region, with sufficient surface area to anchor the expandable member." *See Diederich, et al., at col. 16, lines 52-56.* As shown by the arrows A and B in the modified FIG. 4 of Diederich, et al., below, which depict the distance between the ostium of the pulmonary vein and the mitral valve, the expandable member 170 is spaced from the mitral valve by a large amount relative to the size of the expandable member 170. Furthermore, the expandable member 170 is expanded so as to anchor itself to the inner walls of the pulmonary vein and provide surface-to-surface contact between the ablation band 152 and the pulmonary vein. Accordingly, Applicants submit that the

expandable member does not and cannot exert a compressive force on the mitral valve annulus as recited in claim 1.

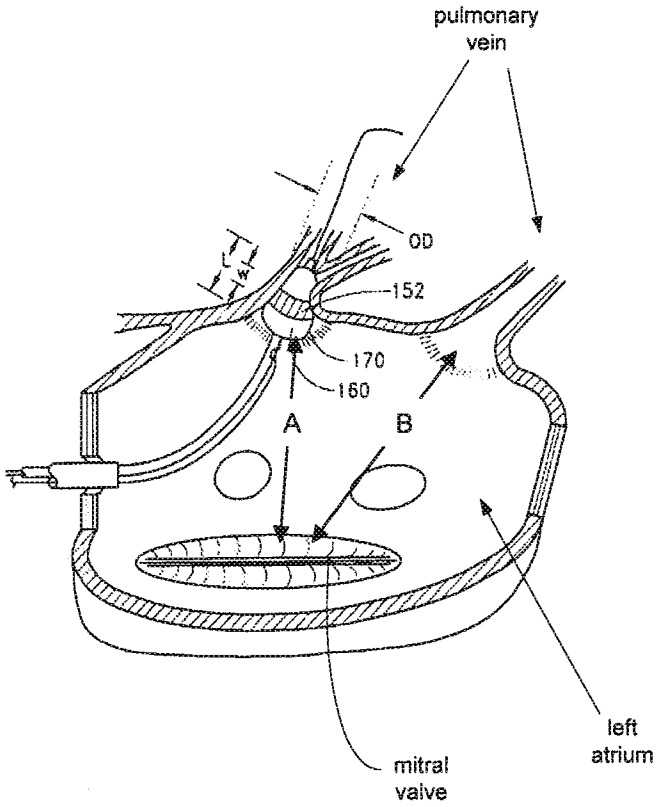

FIG. 4 of Diederich, et al., (modified by Applicants)

The Examiner asserts the following on page 6 of the final Office Action:

> The Applicant contends that the Diederich reference does not disclose its device exerting a compressive force on the mitral valve annulus. The examiner respectfully disagrees. Diederich et al. states that its device may be used in a variety of procedures affecting different areas of the heart. The device may be used on the left atrium and the mitral valve as described in col. 14, lines 23-65.

The section of Diederich, et al., to which the Examiner refers describes methods of directing the ablation device to the left atrium with a guiding catheter. In one method, the catheter is first inserted in the right atrium and then inserted in the left atrium through the fossa ovalis. *See Diederich, et al., col. 14, lines 23-49.* In an alternative method, the catheter is

"advanced through the aorta, around the aortic arch, into the ventricle, and then into the left atrium through the mitral valve." *See Diederich, et al., col. 14, lines 50-61.*

In contrast to the Examiner's assertion, Diederich, et al., does not describe the use of the ablation device on the mitral valve. Diederich, et al., describes the left atrium as being the target location for the ablation device prior to the ablation element being positioned in the pulmonary vein. Accordingly, Diederich, et al., describes reaching the left atrium with two different methods. *See Diederich, et al., col. 14, lines 23-61.* The second of the two methods involves guiding the catheter through the mitral valve to reach the left atrium. *See Diederich, et al., col. 14, lines 60-61.* Therefore, in contrast to the Examiner's assertion, Diederich, et al., does not describe using the ablation device on the mitral valve.

Even, moreover, if some small force would be exerted on the mitral valve annulus during passage of the guide catheter through the mitral valve, such a force would *expand* the mitral valve annulus rather than *compress* the mitral valve annulus.

Based on the foregoing, Applicants submit that Diederich, et al., does not describe "manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus" as recited in claim 1.

iii. Diederich, et al., does not describe "assessing mitral valve regurgitation in response to the monitoring step; and adjusting the prosthesis to a third configuration different from the second configuration in response to the assessing step" as recited in claim 1.

In rejecting claim 1, the Examiner asserts that Diederich, et al., discloses "monitoring and assessing hemodynamic function to adjust the prosthesis to a third configuration or maintain its current configuration (col. 19, lines 54 through col. 20, lines 8)." *See final Office Action, page 2.* Applicants filed a response on January 28, 2009, in which Applicants responded to the above assertion by the Examiner. In particular, Applicants argued that the treatment described in Diederich, et al., and the device used for the treatment is for creating a circumferential conduction block at the ostium of the pulmonary vein in order to block electrical conduction along the longitudinal axis of the pulmonary vein wall and into the left atrium for treating atrial arrhythmia. *See Diederich, et al., at col. 11, line 66 to col. 12 line 5.* Accordingly, Applicants

argued that the treatment steps described in Diederich, et al., have no bearing on mitral valve regurgitation or assessing mitral valve regurgitation based on monitoring hemodynamic function.

In response to Applicants' arguments, the Examiner asserts the following:

> The Applicant further contends that the Diederich reference does not disclose assessing mitral valve regurgitation. However, the Diederich et al. reference describes monitoring conduction, temperature, and blood flow through the location of the device (please see col. 19, line 34-col.20, line 8; col. 37, 50-col. 38, line 25). As the device may be located within mitral valve and the left atrium the blood flow and therefore, the regurgitation levels, through these areas will be monitored as well.

See Office Action, page 6 (emphasis added).

The first section of Diederich, et al., to which the Examiner refers (i.e., col. 19, line 34 to col. 20, line 8) discloses that "electrical signals along the pulmonary vein are monitored with a sensing element before and after ablation according to steps (8) and (9), respectively." *See Diederich, et al., FIG. 9 and col. 19, lines 56-58.* Diederich, et al., discloses that the signals can confirm whether the pulmonary vein chosen for the ablation procedure contains an arrhythmogenic origin in the pulmonary vein. *See Diederich, et al., col. 19, lines 60-62.* "A test electrode may also be used in a 'post ablation' signal monitoring method according to step (10)." *See Diederich, et al., FIG. 9 and col. 20, lines 28-30.* Therefore, the first section of Diederich, et al., to which the Examiner refers discloses measuring electrical signals in the pulmonary vein with electrodes.

The second section of Diederich, et al., to which the Examiner refers (i.e., col. 37, line 50 to col. 38, line 25) is directed to a method of cooling the ablated tissue by using the inflation fluid of the expandable element 170. In particular, Diederich, et al., discloses that if the targeted tissue is maintained below a desired temperature, more power can be deposited in the tissue for greater penetration. *See Diederich, et al., at col. 38, lines 4-7.* To maintain the targeted tissue below a certain temperature, Diederich, et al., discloses circulating the fluid used to inflate the expandable element through a heat exchanger in order to remove heat from the fluid, and thus cooling the target tissue when the fluid is circulated back to the expandable element. *See Diederich, et al., at col. 37, line 60 to col. 38, line 4.* Therefore, the second section of Diederich,

et al., to which the Examiner refers disclose measuring the temperature of the tissue at the ablation site.

As discussed above, Diederich, et al., only discloses measuring electrical signals and temperature at the location of tissue ablation. Thus, in contrast to the Examiner's assertion, Diederich, et al., does not describe measurement of blood flow through the left atrium or at the mitral valve in order to assess mitral valve regurgitation.

Based on the foregoing, Applicants submit that Diederich, et al., does not describe "assessing mitral valve regurgitation in response to the monitoring step; and adjusting the prosthesis to a third configuration different from the second configuration in response to the assessing step" as recited in claim 1.

For the foregoing reasons, Applicants respectfully request that the Examiner's rejection of claim 1 as being anticipated by Diederich, et al., be reversed.

B. Dependent Claims 2-5 and 12-18 are also patentable.

In view of the above arguments, Applicants respectfully submit that dependent claims 2-5 and 12-18 are also patentable over Diederich, et al., either alone or in view of various secondary references applied by the Examiner.

C. Claims 6-11 are patentable over Diederich, et al., in view of Wright.

Claim 6 recites "the step of locking the prosthesis to retain a compressive force on the annulus following the adjusting step." In rejecting claim 6, the Examiner admits that "Diederich et al. does not teach locking the prosthesis in a certain configuration." The Examiner asserts though that Wright teaches, at col. 1, line 40 through col. 3, line 53, "mitral annuloplasty rings in which the rings are held in place by the various means claimed by the Applicant . . . for the purpose of affixing the necessary parts of the prosthesis in their appropriate positions." The Examiner then concludes that "it would have been obvious to one of ordinary skill in the art at the time the invention was made, to modify the device of Diederich et al. by using locking means in order to affix the necessary parts of the prosthesis in their appropriate positions." *See final Office Action at page 3.* Applicants disagree with the Examiner for the following reasons.

One of ordinary skill in the art would not have modified the device of Diederich, et al., according to the teachings of Wright in the way the Examiner proposes because such a modification would render the device of Diederich, et al., unsatisfactory for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *MPEP 2143.01(V).*

Wright discloses a holder for adjustable mitral and tricuspid annuloplasty rings. "Adjustable annuloplasty rings contain internal drawstrings that allow the diameter of the ring to be reduced following the suturing of the ring into the annulus, to minimize any residual regurgitation." *See Wright at col. 1, lines 10-15.* After the annuloplasty rings are sutured into the valve annulus, the drawstring can be pulled to reduce the circumference of the ring. *See Wright at col. 1, lines 16.* The drawstring is then tied to fix the circumference of the ring. *See Wright at col. 1, lines 46-49.* The holder disclosed in Wright "will prevent the needles of the implantation sutures from interfering with the adjusting drawstrings of said annuloplasty ring." *See Wright at col. 1, lines 41-45.* The section of Wright to which the Examiner refers describes the procedure for implanting the annuloplasty ring into the valve annulus with the disclosed holder. *See Wright at col. 2, line 63 to col. 3, line 53.* The only "locking means" disclosed in Wright as the Examiner asserts are the suturing of the annuloplasty ring into the valve annulus, and the tying of the drawstring to maintain the size of the circumference of the ring after implantation.

Referring to FIG. 4 of Diederich, et al., and as described in detail above, the expandable member 170 is positioned in the pulmonary vein and inflated in order to anchor the expandable member and to provide surface-to-surface contact between the ablation band 152 and the inner wall of the pulmonary vein. Furthermore, referring to FIGS. 8a-8d of Diederich, et al., the expandable element can be moved from one pulmonary vein to the other and linearly in the left atrium for creating multiple circumferential and linear lesions. *See Diederich, et al., at col. 18, line 63 to col. 19, line 53.*

One of ordinary skill in the art would not have sutured the expandable member 170 including the ablation element 160 to the inner wall of the pulmonary vein as taught by Wright

because the expandable member would then no longer be moveable in the pulmonary vein and the left atrium in order to create multiple lesions. Furthermore, suturing the expandable member 170 to the inner wall of the pulmonary vein as taught by Wright would prevent the expandable member 170 from being freely inflated and deflated to provide sufficient surface-to-surface contact between the ablation band 152 and the inner wall of the pulmonary vein.

One of ordinary skill in the art would not moreover have provided a drawstring as taught by Wright on the ablation device of Diederich, et al., including the expandable member 170 because such a modification would fix the expandable member 170 in a fixed configuration, thereby preventing inflation and deflation of the expandable member as desired. The circumferential size of the ablation element 160 of Diederich, et al., is adjustable by inflating and deflating the expandable member 170 depending on the circumference of the tissue area where lesions are to be formed. If a drawstring is provided on the expandable member 170 such that tying the drawstring fixes the circumference of the expandable member 170, upon movement of the expandable member 170 to an adjacent tissue region that requires further inflation of the expandable member 170, the drawstring would prevent expansion of the expandable member. Accordingly, the expandable member 170 would not properly function as intended by Diederich, et al.

Applicants further submit that the annuloplasty ring of Wright is a prosthesis, which is permanently affixed into the valve annulus. In contrast, the ablation device of Diederich, et al., is not a prosthesis and is not implanted in a fixed location with sutures or with similar methods of fixing a prosthesis to tissue. The device of Diederich, et al., is removed from the body after creating the desired lesions. Furthermore, the ablation device of Diederich, et al., is adjustable and configurable so as to capable of adapting to the inner circumference of the pulmonary vein at different locations along the pulmonary vein. Therefore, Applicants submit that one of ordinary skill in the art would not have provided the "locking means" of Wright as asserted by the Examiner in the device of Diederich, et al., because the device of Diederich, et al., would become unsatisfactory for its intended purpose.

For the foregoing reasons, Applicants submit that claim 6 is patentable over Diederich, et al., in view of Wright. Because claims 7-11 depend on claim 6, claims 7-11 are also patentable over Diederich, et al., in view of Wright.

3. The Examiner's rejection of claims 19-37 should be reversed.

A. Diederich, et al., does not anticipate claims 19, 21-23, and 30.

Claim 19 is reproduced below with the limitations discussed herein shown underlined:

> A method of remodeling a mitral valve annulus to reduce mitral valve regurgitation, comprising the steps of:
>
> advancing an adjustable prosthesis in a first configuration to a position adjacent the mitral valve annulus;
>
> manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation;
>
> monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration;
>
> assessing the degree of regurgitation in response to the monitoring step; and
>
> fixing the prosthesis in the second configuration in response to the assessing step.

As discussed in detail below, Applicants submit that Diederich, et al., does not describe the above underlined limitations of claim 19.

i. Diederich, et al., does not describe "[a] method of remodeling a mitral valve annulus to reduce mitral valve regurgitation" as recited in claim 19.

Diederich, et al., is directed to "a circumferential ablation device assembly which is adapted to treat patients with atrial arrhythmia by forming a circumferential conduction block in a pulmonary vein which blocks electrical conduction along the longitudinal axis of the pulmonary vein wall and into the left atrium." *See Diederich, et al., col. 11, line 67 to col. 12, line 5.* Accordingly, Diederich, et al., is directed to method of forming a circumferential conduction block in a pulmonary vein for blocking electrical conduction in the pulmonary vein. Therefore, Diederich, et al., does not describe "[a] method of remodeling the mitral valve annulus in order to reduce mitral valve regurgitation" as recited in the preamble of claim 19.

ii. Diederich , et al., does not describe "manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation" as recited in claim 19.

For the reasons set forth above in section VII.2.A.ii regarding patentability of claim 1 over Diederich, et al., Applicants submit that Diederich, et al., does not describe "manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation" as recited in claim 19.

iii. Diederich, et al., does not describe "monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration; assessing the degree of regurgitation in response to the monitoring step; and fixing the prosthesis in the second configuration in response to the assessing step" as recited in claim 19.

For the reasons set forth above in section VII.2.A.iii regarding patentability of claim 1 over Diederich, et al., Applicants submit that Diederich, et al., does not describe "monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration; assessing the degree of regurgitation in response to the monitoring step; and fixing the prosthesis in the second configuration in response to the assessing step" as recited in claim 19.

For the foregoing reasons, Applicants respectfully request that the Examiner's rejection of claim 19 as being anticipate by Diederich, et al., be reversed.

B. Dependent Claims 20-23 and 30-37 are also patentable.

In view of the above arguments, Applicants respectfully submit that dependent claims 20-23 and 30-37 are also patentable over Diederich, et al., either alone or in view of various secondary references applied by the Examiner.

C. Claims 24-29 are patentable over Diederich, et al., in view of Wright.

For the reasons set forth above in section VII.2.C regarding patentability of claims 6-11 over Diederich, et al., in view of Wright, Applicants submit that claims 24-29 are patentable over Diederich, et al., in view of Wright.

VIII. CONCLUSION

Based on the foregoing, Applicants respectfully submit that claims 1-37 are patentable over the applied references. Accordingly, Applicants respectfully request that the rejection of claims 1-37 be reversed.

Respectfully submitted,

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SM/rmw

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IX. CLAIM APPENDIX

1. (Previously Presented) A method of treating a patient, comprising the steps of:

transluminally advancing a prosthesis in a first configuration into the coronary sinus;

manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus;

monitoring hemodynamic function while the prosthesis is in the second configuration;

assessing mitral valve regurgitation in response to the monitoring step; and

adjusting the prosthesis to a third configuration different from the second configuration in response to the assessing step.

2. (Previously presented) The method as in claim 1, further comprising the step of percutaneously accessing the venous system prior to the transluminally advancing step.

3. (Previously presented) The method as in claim 2, wherein the accessing step is accomplished by accessing one of the internal jugular, subclavian or femoral veins.

4. (Previously presented) The method as in claim 1, wherein the manipulating step comprises axially moving a forming element with respect to the prosthesis, to bend the prosthesis.

5. (Previously presented) The method as in claim 1, wherein the transluminally advancing step is accomplished using a catheter.

6. (Previously presented) The method as in claim 1, further comprising the step of locking the prosthesis to retain a compressive force on the annulus following the adjusting step.

7. (Previously presented) The method as in claim 6, wherein the locking step comprises moving an engagement surface from a disengaged configuration to an engaged configuration.

8. (Previously presented) The method as in claim 6, wherein the locking step comprises providing an interference fit.

9. (Previously presented) The method as in claim 6, wherein the locking step comprises providing an adhesive bond.

10. (Previously presented) The method as in claim 6, wherein the locking step comprises providing a knot.

11. (Previously presented) The method as in claim 6, wherein the locking step comprises providing a compression fit.

12. (Previously presented) The method as in claim 1, further comprising the steps of first measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the advancing step.

13. (Previously presented) The method as in claim 1, wherein the step of monitoring hemodynamic function is accomplished using transesophageal echo cardiography.

14. (Previously presented) The method as in claim 1, wherein the step of monitoring hemodynamic function is accomplished using surface echo cardiographic imaging.

15. (Previously presented) The method as in claim 1, wherein the step of monitoring hemodynamic function is accomplished using intracardiac echo cardiographic imaging.

16. (Previously presented) The method as in claim 1, wherein the step of monitoring hemodynamic function is accomplished using fluoroscopy with radiocontrast media.

17. (Previously presented) The method as in claim 1, wherein the step of monitoring hemodynamic function is accomplished using left atrial or pulmonary capillary wedge pressure measurements.

18. (Previously presented) The method as in claim 1, further comprising the step of determining an ongoing drug therapy taking into account post implantation hemodynamic function.

19. (Previously Presented) A method of remodeling a mitral valve annulus to reduce mitral valve regurgitation, comprising the steps of:

advancing an adjustable prosthesis in a first configuration to a position adjacent the mitral valve annulus;

manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation;

monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration;

assessing the degree of regurgitation in response to the monitoring step; and

fixing the prosthesis in the second configuration in response to the assessing step.

20. (Previously Presented) The method of remodeling a mitral valve annulus as in claim 19, wherein sufficient manipulating is performed to achieve at least a one grade reduction in regurgitation.

21. (Previously presented) The method as in claim 19, further comprising the step of percutaneously accessing the venous system prior to the transluminally advancing step.

22. (Previously presented) The method as in claim 21, wherein the accessing step is accomplished by accessing one of the internal jugular, subclavian or femoral veins.

23. (Previously Presented) The method as in claim 19, wherein the manipulating step comprises axially moving a forming element with respect to the prosthesis, to bend the prosthesis.

24. (Previously Presented) The method as in claim 19, further comprising the step of locking the prosthesis to retain a compressive force on the annulus following the manipulating step.

25. (Previously presented) The method as in claim 24, wherein the locking step comprises moving an engagement surface from a disengaged configuration to an engaged configuration.

26. (Previously presented) The method as in claim 24, wherein the locking step comprises providing an interference fit.

27. (Previously presented) The method as in claim 24, wherein the locking step comprises providing an adhesive bond.

28. (Previously presented) The method as in claim 24, wherein the locking step comprises providing a knot.

29. (Previously presented) The method as in claim 24, wherein the locking step comprises providing a compression fit.

30. (Previously presented) The method as in claim 19, further comprising the steps of first measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the transluminally advancing step.

31. (Previously presented) The method as in claim 19, wherein the monitoring step is accomplished using transesophageal echo cardiography.

32. (Previously presented) The method as in claim 19, wherein the monitoring step is accomplished using surface echo cardiographic imaging.

33. (Previously presented) The method as in claim 19, wherein the monitoring step is accomplished using intracardiac echo cardiographic imaging.

34. (Previously presented) The method as in claim 19, wherein the monitoring step is accomplished using fluoroscopy with radiocontrast media.

35. (Previously presented) The method as in claim 19, wherein the monitoring step is accomplished using left atrial or pulmonary capillary wedge pressure measurements.

36. (Previously presented) The method as in claim 19, further comprising the step of determining an ongoing drug therapy taking into account post implantation hemodynamic function.

37. (Previously presented) The method as in claim 36, comprising measuring residual regurgitation following implantation and formulating an ongoing drug therapy taking into account the residual regurgitation.

X. EVIDENCE APPENDIX

NONE

XI. RELATED PROCEEDING APPENDIX

NONE